

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sæbo et al.

Serial No.:

09/132,593

Group No.: 1617

Examiner: D. Faulkner

Filed: Entitled: 8/11/98 CONJUGATED LINOLEIC ACID ALKYL

ESTERS IN FEEDSTUFFS AND FOOD

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231, on April 10, 2000.

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 2,350,583;
- U.S. Patent No. 2,242,230;
- U.S. Patent No. 4,381,264;
- U.S. Patent No. 5,554,646;
- U.S. Patent No. 5,428,072;
- U.S. Patent No. 3,162,658;
- U.S. Patent No. 4,164,505;
- British Patent No. 558,881.

- Klein and Crauer, JAOCS 51: 382A-385A (1971);
- Burkhardt, JAOCS 48: 697-699 (1971);
- Birt, et al., Cancer Res., 52: 2035s (1992);
- Ha, et al., Cancer Res., 50: 1097 (1990);
- Cowan, JAOCS, 72: 492 (1950);
- Kass, et al., J. Am. Chem. Soc., 61: 4829 (1939);
- Radlove, et al., Ind. Eng. Chem., 38: 997 (1946);
- Sullivan, JAOCS, 53: 359 (1976);
- Handbook of Soy Oil Processing and Utilization, Erickson et al., eds., AOCS,
 Champaign, 1980. This publication is not provided but is available upon Examiner's request.;
- McGraw-Hill Encyclodpedia of Science and Technology, McGraw-Hill Book Co.,
 N.Y. 1996 (5th ed.). This publication is not provided but is available upon
 Examiner's request.;

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- U.S. Patent No. 6,015,833 issued 01/18/00 to Saebo et al.
- EP patent application No. 839,897 to Rinoru Oil Mills Co., LTD. describes a method for producing conjugated linoleic acid by alkali isomerization of linoleic acid contained in a fat or oil. This application does not disclose the isomer composition of the conjugated linoleic acid.
- U.S. Patent No. 5,986,116 to Iwata *et al.*, describes a method for producing conjugated linoleic acid by alkali isomerization of linoleic acid contained in a fat or oil. This application does not disclose the isomer composition of the conjugated linoleic acid.
- Scholfield and Koritalia, "A Simple Method for Preparation of Methyl trans-10,cis-12 Octadecadienoate," JOACS 47(8): 303 (1970) describe the preparation of methyl t10,c12 octadecadienoate from purified methyl linoleate. Scholfield and Koritalia do not disclose an isomerized composition containing less than 2% of 11,13-

- octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, transoctadecadienoic acid alkyl ester.
- EP Application No. 902,082 to Loders describes a method for production of material rich conjugated isomers of long chain polyunsaturated fatty acids.
- PCT Patent Application No. WO 97/18320 to Loders describes an enzymatic method for preparing CLA compositions enriched for the t10,c12 isomer or c9,t11 isomer. This application does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- PCT Patent Application WO 98/49129 to Henkel describes in the abstract triglycerides containing at least one conjugated linolenic acid radical. This application does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Sugano *et al.*, "Conjugated Linoleic Acid Modulates Tissue Levels of Chemical Mediators and Immunoglobulins in Rats," Lipids, 33(5):521-27 (1998), describe CLA produced by non-aqueous alkali isomerization which contains 18.6% trans-trans isomers. Sugano, *et al.* do not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Pat. No. 5,856,149 to Pariza *et al.*, describes an enzymatic method for producing c9,t11 CLA. Pariza, *et al.* do not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Pat. No. 5,855,917 to Cook *et al.*, describes a method for controlling body fat and body weight by administering conjugated 20 carbon fatty acids. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.

- U.S. Pat. No. 5,851,572 to Cook *et al.*, describes a method of increasing fat firmness in animals using non-aqueous alkali isomerized CLA. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Pat. No. 5,827,885 to Cook *et al.*, describes a method of treating animals to increase immune effector cells using enzymatically synthesized c9,t11 CLA. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Pat. No. 5,814,663 to Cook *et al.*, describes a method of maintaining body fat in animals using non-aqueous alkali isomerized CLA. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Pat. No. 5,804,210 to Cook *et al.*, describes a method of treating an animal to increase bone strength through administration of CLA. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Matreya Catalog, 1997, pp. 33-34, describes a purified preparation of c9,t11 CLA. This publication does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Hudtwalcker & Co. AS Technical Data Sheet, exact publication date unknown, describes CLA compositions with various levels of CLA. This publication does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.

- Selin CLA Product Literature, 1/97, describes triglycerides incorporating CLA. This publication does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Lipid Technology Newsletter, Peter J. Barnes, Ed., Vol. 4, No. 5, pp 85-86 (October, 1998), describes a Loders CLA product which contains approximately 80% of t10,c12 and c9,t11 isomers and minor amounts of other isomers. This publication does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Natural Lipids Ltd. AS Technical Data Sheet, 1/20/97, describes CLA compositions with varying amounts of CLA. This publication does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Ron Udell, Information About Conjugated Linoleic Acid, published by Soft Gel
 Technologies Incorporated, exact publication date unknown, describes the analysis of
 CLA products. This publication does not disclose a composition containing alkyl
 esters of conjugated linoleic acid.
- PCT Patent Application WO 97/46230 to Wisconsin Alumni Research Foundation, describes a method for maintaining an existing level of body fat or body weight in a human through the administration of CLA. This application does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 5,208,356 to Pariza, et al. describes the use of salts and esters of CLA as antioxidants and inhibitors of mold growth. A method of making the c9,t11 isomer of CLA is also described. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.

- European Patent Application No. 440,325 to Wisconsin Alumni Research Foundation describes a method of chelalating metals in solution using CLA. This application does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, transoctadecadienoic acid alkyl ester.
- PCT Patent Application No. WO 98/05318 to Wisconsin Alumni Research Foundation describes the use of CLA to maintain or enhance the mineral content of the bones of an animal. This application does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 5,760,082 to Cook, et al. describes a dietetic food containing CLA.
 This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 5,554,646 to Cook, *et al.* describes the use of CLA to reduce body fat and preserve or increase body protein in an animal. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 5,585,400 to Cook, *et al.* describes the use of CLA to prevent or treat the adverse affects of type I or IgE mediated hypersensitivity and to preserve white blood cells. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 5,674,901 to Cook, *et al.* describes the use of CLA to maintain or elevate CD-4 and CD-8 levels in animals. A method for the production of CLA using bacteria isolated from a rat colon is also described. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl

- ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 5,428,072 to Cook, *et al.* describes a method of enhancing weight gain and feed efficiency in an animal through the administration of CLA. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- U.S. Patent No. 3,729,379 to Emken describes a method for producing hydroxy-conjugated fatty acids from linoleic acid soaps using dimethyl sulfoxide and soybean lipoxygenase. This patent does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Belury, "Conjugated dienoic linoleate: a polyunsaturated fatty acid with unique chemoprotective properties," Nutr. Rev. 53: 83-9 (1995), describes the chemical background and chemoprotective properties of CLA. Belury does not disclose an isomerized composition containing less than 2% of 11,13-octadecadienoic acid alkyl ester, 8,10-octadecadienoic acid alkyl ester, and trans, trans-octadecadienoic acid alkyl ester.
- Garcia, et al., "Enrichment of butteroil with conjugated linoleic acid via enzymatic interesterification (acidolysis) reactions," Biotechnology letters 20:393 (1998) describe the incorporation of conjugated linoleic acids into butteroil triacylglycerides by microbial lipases. Garcia, et al. do not disclose an isomerized CLA composition containing less than 2% of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid.
- E.P. Patent application No. 779,033 A1 describes as edible fat spread containing triglycerides of CLA. This application does not disclose an isomerized CLA composition containing less than 2% of 11,13-octadecadienoic acid and 8,10octadecadienoic acid.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that anyone or more of these citations constitutes prior art.

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